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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/644,201 | 08/22/2000 | Gerardo V. Noriega | 19635-000210US | 1112 |

20350 7590 05/17/2004

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EXAMINER

NGUYEN, VI X

| | |
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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/644,201 | Applicant(s) NORIEGA ET AL. | |
| | Examiner Victor X Nguyen | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-24,28-39,67-69 and 72-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-24,28-39,67-69 and 72-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____ |
|--|--|

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/05/2004 has been entered.
2. The status of claim 9 has been canceled in 4/5/2004 of the **remarks section**. However in **Listing of Claims**, claims 10-12 depend on claim 9. Clarification is requested.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-24,28-39,67-69 and 72-81 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Adams (U.S.6,312,438).

As to claims 1, 80 and 81, Adams discloses in figs 1-3 and col. 3, lines 15-67, an assembly having all the limitation as recited in the above listed claim, including: a guide wire (item 12 is a hollow, flexible tube for insertion into a body cavity or vessel to allow the passage or distend a passageway); a drive shaft (34), wherein said drive shaft (34) includes a distal tip (36) which can create a path through stenotic material. As best seen on fig. 1, item 16 can be

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characterized as a housing that is coupled to a proximal end of the guidewire. The system of Adams could be made a guidewire that has a passage with an outer diameter between 0.009 inches and 0.035 inches. It has been held that changes in size only require routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the system for crossing occlusive material with a passage that has an outer diameter between 0.009 inches and 0.035 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, with regard to the housing being removably coupled to a proximal end of the guide-wire, it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Adams with the housing removably coupled to the proximal end of the guide-wire, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Nerwin v. Erlichman, 168 USPQ 177, 179.

As to claims 4-8, 21-23, 68-69 and 72, wherein the assembly further includes a motor (labeled in col. 6, lines 55-64) coupled to the drive shaft. The drive shaft (34) can be manually rotated. The distal tip (36) is flattened and twisted (50, fig. 2). The distal tip (36) has a width which is larger than the width of the drive shaft; and wherein the hollow guide wire (12) is steerable.

As to claims 9-12, wherein a housing (16) coupled to the proximal end of the hollow guide wire; wherein said housing (16) including an actuator (labeled in col. 10, lines 1-4), wherein the drive shaft (34) defines a longitudinal axis and the actuator moves the drive shaft

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along the longitudinal axis; and wherein the housing (16) includes an aspiration port (74) coupled to the hollow guide wire.

As to claims 13-15, wherein the guide wire (12) is in stationary position while the drive shaft (34) facilitates transportation of a removed occlusive material. The distal tip of the drive shaft is radio-opaque (labeled in col. 10, lines 53-65).

As to claims 16-19, wherein a support system having a distal end, wherein the hollow guide wire (12) passes through the support system in order to allow the distal tip is positioned beyond the distal end of the hollow guide wire and the support system; wherein the support system includes placing means disposed near distal end of the support system within the body lumen; and wherein the hollow guide wire is through a vasculature and the drive shaft (34) defines a longitudinal axis, wherein the distal tip is deflected off the longitudinal axis.

Claims 20, 31 and 67 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Adams (U.S. 6,312,438).

As to claims 20, 31 and 67, Adams disclose in figs 1-3 and col. 3, lines 15-67, an assembly having all the limitation as recited in the above listed claims, including: a hollow guide wire (12); a rotating mechanism coupled to the drive shaft (34); wherein an actuator (labeled in col. 10, lines 1-4) coupled to the drive shaft (34); and wherein the activation of the actuator advances the rotatable drive shaft (34) from a retracted position to an extended position; wherein said drive shaft (34) including a flattened and twisted distal tip (36, fig. 2) can be rotated and created a path through stenotic material. As best seen on fig. 1, item 16 can be characterized as a housing that is coupled to a proximal end of the guidewire. The system of Adams could be made a guidewire that has a passage with an outer diameter between 0.009 inches and 0.035 inches. It

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has been held that changes in size only require routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the system for crossing occlusive material with a passage that has an outer diameter between 0.009 inches and 0.035, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Furthermore, with regard to the housing being removably coupled to a proximal end of the guide-wire, it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Adams with the housing removably coupled to the proximal end of the guide-wire, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

As to claim 24, wherein the distal tip portion includes a spiral with a blunt tip (fig. 2).

As to claims 28-30, wherein the rotating mechanism and actuator (labeled in col. 10, lines 1-4) are coupled together such that the drive shaft (34) is rotated and advanced simultaneously; and wherein the hollow guide wire (12) is configured to aspirate fluids and debris from stenosis.

As to claims 73-74, wherein the kit further a support system is sized to receive the hollow guide wire (12) and position the distal end of the guide wire is adjacent the occlusion; and wherein the support system includes an atherectomy catheter.

As to claims 76-79, wherein a motor can be coupled to the rotatable drive shaft (34); and wherein the housing (16) is coupled to the hollow guide wire (12) through a luer (35, fig. 1).

Claims 1, 20, 31, 67 and 80 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Passafaro et al (U.S. 6,156,046).

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As to claims 1, 20, 31, 67 and 80, Passafaro et al disclose in figs 1, 1a, 2, 3, abstract and col. 11, lines 7-67, an assembly having all the limitation as recited in the above listed claims, including: a hollow guide wire (32); a rotating mechanism coupled to the drive shaft (52); wherein an actuator (42) coupled to the drive shaft (52); and wherein the activation of the actuator advances the rotatable drive shaft (52) from a retracted position to an extended position; wherein said drive shaft (52) including a flattened and twisted distal tip (96, fig. 3) can be rotated and created a path through stenotic material. As best seen on fig. 1, item 16 can be characterized as a housing that is coupled to a proximal end of the guidewire.

The system of Passafaro et al could be made a guidewire that has a passage with an outer diameter between 0.009 inches and 0.035 inches. It has been held that changes in size only require routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the system for crossing occlusive material with a passage that has an outer diameter between 0.009 inches and 0.035 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, with regard to the housing being removably coupled to a proximal end of the guide-wire, it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Adams with the housing removably coupled to the proximal end of the guide-wire, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

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Claim 75 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Adams (U.S. 6,312,438) in view of Noriega (U.S. 6,059,767).

As to claim 75, Adams teaches all aspect of the claimed invention except including a second guide wire. Noriega teaches a second guide wire (labeled in col. 4, lines 45-67 and col. 5, lines 1-14) in order to improve the efficiency of the catheter and to provide a better position at a selected tissue site. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adams by adding the second guide wire in order to improve the efficiency of the catheter and to provide a better position at a selected tissue site.

Response to Amendment

4. Applicant's remarks with respect to claims 1, 20, 31, 67 and 80-81 have been considered but are moot in view of new ground(s) of rejection. Applicant is asked to please refer to the modified prior art rejection above wherein examiner addresses applicant's concerns regarding prior art rejection. Adams discloses in figs 1-3 and col. 3, lines 15-67, an assembly having all the limitation as recited in the above listed claim, including: a guide wire (item 12 is a hollow, flexible tube for insertion into a body cavity or vessel to allow the passage or distend a passageway); a drive shaft (34), wherein said drive shaft (34) includes a distal tip (36) which can create a path through stenotic material. As best seen on fig. 1, item 16 can be characterized as a housing that is coupled to a proximal end of the guidewire. The system of Adams could be made a guidewire that has a passage with an outer diameter between 0.009 inches and 0.035 inches. It has been held that changes in size only require routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the system for crossing occlusive material with a passage that has an outer diameter between

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0.009 inches and 0.035 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, with regard to the housing being removably coupled to a proximal end of the guide-wire, it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Adams with the housing removably coupled to the proximal end of the guide-wire, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Nerwin v. Erlichman, 168 USPQ 177, 179.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen

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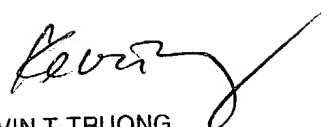
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Examiner

Art Unit 3731

Vn \checkmark

May 7, 2004


KEVIN T. TRUONG
PRIMARY EXAMINER

5/7/04